REMARKS

I. STATUS OF THE CLAIMS

Claims 1, 2 and 6-93 are pending in the application, of which claims 58-81 and 83-89 are withdrawn from consideration as being drawn to non-elected invention.

Claim 1 is the sole independent claim currently under examination.

Claims 1-10, 14, 15, 17, 19-25, 32, 33, 34, 35-46, 50-54, 55-57, 82 and 90-93 stand rejected under 35 U.S.C. § 102.

Claims 11-13, 16, 18, 26, 27, 28, 29, 30, 31, and 47-49 stand rejected under 35 U.S.C. § 103.

It is believed that any amendments herein do not involve the addition of any new subject matter.

II. CLAIMS 1, 2 6-10, 14, 15, 17, 19-25, 32, 35-46, 55-57 AND 90-93 ARE NOT ANTICIPATED UNDER 35 U.S.C. § 102(b) BY SIMMET ET AL. (US . 5,961,503) BECAUSE THE APPLIED PRIOR DISCLOSE THE LIMITATIONS OF THE APPLICANTS' INVENTON.

Claims 1-10, 14, 15, 17, 19-25, 32, 35-46, 55-57 and 90-93 were rejected under 35 U.S.C. § 102(b) as being anticipated by Simmet et al U.S. Patent No. 5,961,503 (hereinafter " Simmet "). In particular, the Office Action states:

> With respect to claim 1: With regard to the limitations "a device for collecting semen received from a glans penis of a male human individual", "whereby said tapered section accommodates the head of the glans penis" and "adapted for receiving the semen ejaculated from the glans penis", the device of Simmet meets all of the structural limitations of claim 1 as to collection of semen from a mammal (i.e. a boar), and thus is fully capable of collecting semen from the glans penis of a human male, and the tapered section of the device is considered herein to accommodate the head of said glans penis, and the receiving portion of the device of Simmet as claimed is considered herein to be adapted for receiving semen ejaculated from said glans penis, as the device disclosed by Simmet collects another type of mammalian semen. Simmet discloses a device for collecting boar semen. The device comprises a chamber defined by bag 20. said chamber 20

comprising a distal end. a proximal end, and a conduit extending between said distal end and proximal end (Fig. 4). The proximal end has a rim defining an aperture and said distal end having a surface that encloses said conduit. (Fig. 3) At least a portion of said conduit proximal to said proximal end has a tapered shape radially inward defining a tapered section, whereby said tapered section accommodates a boar's penis. (Col. 4, lines 40-42) At least a portion of said conduit proximal to said distal end, specifically at seam 30 is adapted for receiving the semen ejaculated from the boar's penis (Fig. 4). The receiving portion, as can be seen in Fig. 4, defines a reservoir section for the semen. The tapered accommodation section disclosed by Simmet meets all of the claim limitations as to as to a portion near the proximal end that is tapered radially and accommodates the penis of a mammal. The reservoir section is bounded by the two rectangular segments 26,28 and seam 30 (Fig. 2) and is thus configured to prevent loss of any fractions of semen during ejaculation.

(See Office Action, par. 4, pages 3-4)

Applicants respectfully traverse the rejection of claims 1, 2, 6-10, 14, 15, 17, 19-25, 32, 35-46, 55-57 and 90-93 as being anticipated by Simmet because the applied prior art fails to teach or suggest the Applicant's invention, as recited in part in base clam 1 as follows:

i) a human glans penis accommodating device for collecting all fractions of ejaculated semen sample received from the glans penis after masturbation and/or post coital interruption; and/or

ii) said tapered accommodation section is configured to prevent loss of any fractions of semen during ejaculation, and/or

said reservoir section is configured to prevent loss of any fractions of semen during ejaculation.

Regarding the design of the Simmet bag 20 and filter 24, Simmet neither functions nor provides the structure for collecting all fractions of ejaculated semen sample. To the contrary, the filter 24, for example, would actually cause lose of fractions.

Regarding the design of the Simmet bag 20 and filter 24, Simmet neither functions nor provides the structure to prevent loss of any fractions of semen during ejaculation and/or

prevent loss of any fractions of semen during ejaculation as recited in the Applicant's base claim. To the contrary, the filter 24, for example, would actually cause lose of fractions.

For the purpose of background only, as stated in the specification at page 8, lines 24-30,

> Loss of initial fractions may significantly affect semen analysis values, particularly sperm count and motility of a semen sample. Therefore, it is very important to recover the entire ejaculate, specially the sperm rich initial epididymal fluid fractions for sample evaluation despite the manner of collection. Unfortunately, however, no single device is available that prevents loss of semen samples during sample collection and thus optimizes semen collection and subsequent testing.

Accordingly, Simmet fails to suggest or teach the present invention as claimed and taught in the specification.

For the purpose of background only, as stated in the specification at page 11, lines 17-30,

> Some of the advantages of some of the embodiments of the present invention semen collection and storage device, and related method of use are multifold. For example, but not limited thereto, freshly ejaculated human semen is a heterogeneous mixture of fluid and gel phases that entrap spermatozoa in a relatively immotile state before liquefaction. During ejaculation, human semen is produced in split fractions which follow a specific sequence of emission with the orgasmic contraetions. The initial fractions are contributed by the Cowper's secretion followed by highly sperm rich epididymal secretions and some prostate secretion, followed by fractions containing mixture of prostatic and seminal vesicular secretions and finally the ejaculate culminates with soft gel-like coagulum primarily contributed by seminal vesicular secretion. The various embodiments of the collection device eliminate the unesthetical condom use during masturbation, prevents loss of sperm rich initial fractions during conventional collection into a test tube or into a bottle and also avoids multiple transfer related sample loss following ejaculation into a condom.

Accordingly, Simmet fails to suggest or teach the present invention as claimed and taught in the specification.

For the purpose of background only, as stated in the specification at page 13, lines 15-19,

> Following ejaculation, the collection device 11 allows spontaneous (or subsequent) liquefaction and complete recovery of ejaculated material, provides the measurement of the ejaculated volume, provides for the mixing of sperm and liquefied seminal plasma components for subsequent semen analysis and cryo-preservation of the sample.

Accordingly, Simmet fails to suggest or teach the present invention as claimed and taught in the specification.

In view of the differences of base claim 1 and Simmet, Applicants respectfully urge that the rejections of claims 1, 2, 6-10, 14, 15, 17, 19-25, 32, 35-46, 55-57 and 90-93 be withdrawn.

III. CLAIMS 1, 33, 34, 50-54 ARE NOT ANTICIPATED UNDER 35 U.S.C. § 102(b) BY FLEURY (US . 5,569,225) BECAUSE THE APPLIED PRIOR DISCLOSE THE LIMITATIONS OF THE APPLICANTS' INVENTON.

Claims 1, 33, 34, 50-54 and 82 were rejected under 35 U.S.C. § 102(b) as being anticipated by Fleury U.S. Patent No. 5,569,225. In particular, the Office Action states:

> With respect to **claim 1:** Fleury discloses a device for collecting semen received from a glans penis of a male human individual. The device comprises a chamber 14, said chamber comprising a distal end, a proximal end, and a conduit extending between said distal end and proximal end. The proximal end has a rim defining an aperture. (Fig. 1) The distal end has a surface adjacent valve 23 that is sealed to the lower end 16 of chamber 14 that encloses said conduit. (Col. 5, lines 25,26) At least a portion of said conduit proximal to said proximal end has a tapered shape radially inward defining a tapered section, whereby said tapered section accommodates female genitalia and thus is considered herein to be able to accommodate the head of the glans penis. (Col. 5, line 66 - Col. 6, line 5) At least a portion of said conduit proximal to said distal end 16 is adapted for receiving the semen ejaculated from the glans penis, said receiving portion defining a reservoir section for the semen. (Col. 5, lines 36-41)

(See Office Action, par. 5, pages10-11)

Applicants respectfully traverse the rejection of claims 1, 33, 34, 50-54 and 82 as being anticipated by Fleury because the applied prior art fails to teach or suggest the Applicant's invention, as recited in part in base clam 1 as follows:

i) a human glans penis accommodating device for collecting all fractions of ejaculated semen sample received from the glans penis after masturbation and/or post coital interruption; and/or

ii) said tapered accommodation section is configured to prevent loss of any fractions of semen during ejaculation, and/or

said reservoir section is configured to prevent loss of any fractions of semen during ejaculation.

Regarding the design of the Fleury chamber 14 and collection bag, Fleury neither functions nor provides the structure for collecting all fractions of ejaculated semen sample. To the contrary, the narrow lower end 16, valve means 23, and lower end 19, for example, would actually cause lose of fractions.

Regarding the design of the Fleury chamber 14 and collection bag, Fleury neither functions nor provides the structure to prevent loss of any fractions of semen during ejaculation and/or prevent loss of any fractions of semen during ejaculation as recited in the Applicant's base claim. To the contrary, the narrow lower end 16, valve means 23, and lower end 19, for example, would actually cause lose of fractions.

Briefly, the application of Fleury is not substantiated. For instance, simply as an example, there is no reference to any of the following elements or items in Fleury: semen, masturbation, intercourse, condoms, fraction, penis, glans penis, liquefaction, ejaculate and ejaculation. There is no correlation between the present invention and Fleury.

For the purpose of background only, as stated in the specification at page 8, lines 24-30,

> Loss of initial fractions may significantly affect semen analysis values, particularly sperm count and motility of a semen sample. Therefore, it is very important to recover the entire ejaculate, specially the sperm rich initial epididymal fluid fractions for sample evaluation despite the manner of collection. Unfortunately, however, no single device is available that prevents loss of semen samples during sample collection and thus optimizes semen collection and subsequent testing.

Accordingly, Simmet fails to suggest or teach the present invention as claimed and taught in the specification.

For the purpose of background only, as stated in the specification at page 11, lines 17-30,

> Some of the advantages of some of the embodiments of the present invention semen collection and storage device, and related method of use are multifold. For example, but not limited thereto, freshly ejaculated human semen

is a heterogeneous mixture of fluid and gel phases that entrap spermatozoa in a relatively immotile state before liquefaction. During ejaculation, human semen is produced in split fractions which follow a specific sequence of emission with the orgasmic contractions. The initial fractions are contributed by the Cowper's secretion followed by highly sperm rich epididymal secretions and some prostatic secretion, followed by fractions containing mixture of prostatic and seminal vesicular secretions and finally the ejaculate culminates with soft gel-like coagulum primarily contributed by seminal vesicular secretion. The various embodiments of the collection device eliminate the unesthetical condom use during masturbation, prevents loss of sperm rich initial fractions during conventional collection into a test tube or into a bottle and also avoids multiple transfer related sample loss following ejaculation into a condom.

Accordingly, Fleury fails to suggest or teach the present invention as claimed and taught in the specification.

For the purpose of background only, as stated in the specification at page 13, lines 15-19,

> Following ejaculation, the collection device 11 allows spontaneous (or subsequent) liquefaction and complete recovery of ejaculated material, provides the measurement of the ejaculated volume, provides for the mixing of sperm and liquefied seminal plasma components for subsequent semen analysis and cryo-preservation of the sample.

Accordingly, Fleury fails to suggest or teach the present invention as claimed and taught in the specification.

Moreover, Applicants respectfully traverse the above-referenced characterizations as the Office Action fails to correlate the applied references to the claimed elements. Applicants respectfully submit that the prima facie case of anticipation and obviousness has neither been presented nor achieved by the Office Action. Applicants submit that the applied references are not accurately interpreted by the Examiner.

MPEP §2131 provides:

> "A claim is anticipated only if each and every element as set froth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as contained in the ... claim." *Richardson v. Suzuki Motor Co.*,

868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim.

For example, the Office Action erroneously recites support alleging Fleury accomplishes Applicant's base claim elements cited above. For instance, contrary to the Office Action, Fleury fails to make any reference to semen or glans penis as recited in the office action, but rather a tapered section corresponding to the exterior of a female and for urine (for example: col. 5, lines 16-24 and col. 6, lines 1-5). Moreover, simply as an overview, there is no reference to any of the following elements or items in Fleury: semen, masturbation, intercourse, condoms, fraction, penis, glans penis, liquefaction ejaculate and ejaculation. There is no correlation between the present invention and Fleury.

In view of the differences of base claim 1 and Fleury, Applicants respectfully urge that the rejections of claims 1, 33, 34, 50-54 and 82 be withdrawn.

Summary

In summary, Simmet and Fleury (and the applied prior art) fails to teach the Applicant's invention as claimed in amended base claim 1. For instance, unlike Simmet and Fleury (and the applied prior art), the Applicant's invention allows for the collection of the complete split ejaculates and entire semen sample. As loss of semen fractions during initial or later collection phase of ejaculation results in substantial errors in sperm count and sperm motility values. For instance, unlike Simmet and Fleury (and the applied prior art), the Applicant's invention allows for the complete semen liquid fraction and coagulum fraction collection and subsequent liquefaction of entire ejaculate in the collection device. For instance, unlike Simmet and Fleury (and the applied prior art), Applicant's invention allows for the accurate collection of all harvested components. For instance, unlike Simmet and Fleury (and the applied prior art), the Applicant's invention allows for the liquefaction of all fractions of ejaculation and sperm count, morphology and motility determination that can be made for the optional recovery for successful intrauterine insemination and in vitro fertilization support to subfertile couples. For instance, unlike Simmet and Fleury (and the applied prior art), the Applicant's invention allows for a

defined aliquot of the semen that may be withdrawn in order to determine accurate sperm concentration.

Moreover, it should be appreciated that other considerations are as follows:

1) Unlike Simmet the present invention device is user-friendly and superior to a condom based collection when masturbation (for example, but not necessarily) is the means of sexual excitement prior to ejaculation. Masturbation and/or intercourse is neither referenced, taught nor suggested in Fleury.

2) With the present invention the recovery of semen samples is 100% unlike condom collection or Simmet collection where semen recovery is only partial (Semen samples are neither referenced, taught nor suggested in Fleury). The present invention device prevents loss of any portion of the ejaculate and is ideal for collecting initial ejaculate fractions which are rich in concentrated sperm which could be used for intra-uterine or intra-cervical insemination. Understanding these advantages of present invention device requires consideration of the use of seminal fluid in diagnostic and therapeutic procedures. It is critically important to obtain all of the initial fraction of the ejaculate in order to obtain an accurate determination of sperm count in diagnostics and to obtain all of the spermatozoa for therapeutic use in IVF, intrauterine insemination, cervical cap application, etc. Unlike Simmet, the present invention device allows for capture of all portions of the ejaculate.....a feature that will also become more critical as new clinical tests are introduced which utilize liquefied seminal fluid to monitor other analytes [such as STI DNAs and proteins; biomarkers of testicular health; i.e. semen serving as a window to monitor health and disease of the male tract]. Ejaculate is neither referenced, taught nor suggested in Fleury.

The ejaculate is a stream of fluids representing secretions of different male accessory glands in order: first fractions: epididymal fluid and sperm, followed by seminal vesicle secretion and prostatic fluids. [It is thought that this sequence of fluid ejaculation has evolved over eons to insure initial deposit the sperm rich epididymal fluid fraction into the vaginal fornix and then follow-on by seminal vesicle fluid gel so as to adhere the sperm rich fraction with a coating of the seminal coagulum over the vaginal surface. During the liquefaction period PSA [a trypsin protease] in the prostatic fraction initiates liquefaction of the seminal gel by acting on the

seminogelins in the seminal vesicle fraction thus allowing a time release of sperm from the seminal coagulum into the cervical os.] In condom collection, because of the way in which semen collects and adheres to both the inside of the condom and the body of the penis, samples obtained with this device may not represent all of the accessory secretions accurately...and thus not allow accurate measurements of sperm count or other seminal fluid biomarkers.

Further, because all of the sperm fraction is captured in present invention device it is superior to condom collection and Simmet collection when sperm counts are low and the liquefied semen will be used subsequently for intrauterine insemination (clinically) or at home by the couple using a cervical cap filled with liquified semen. Sperm fractions are neither referenced, taught nor suggested in Fleury.

3) Taking a condom off and then expressing the semen or puncturing the condom with a syringe, or cutting with a scissors is messy. The single unit present invention device may be designed for collection of ejaculate (semen) without needing a condom and the subsequent liquefaction of semen occurs in the self standing reservoir. Following collection and liquefaction, the liquefied seminal fluid is easily sampled for application to a cervical cap for fertility treatments or sampling with a syringe specifically designed for semen sampling. This self standing feature is particularly useful for at-home users of OTC diagnostics or clinical sampling for point-of-care diagnostics where ease of sampling is required.

4) Unlike Simmet, the present invention device has been designed to be compatible to the broad range of sizes of the glans penis. Because the present invention device may lock onto the glans penis it permits all ejaculate fractions to be collected. The present invention device prevents backflow of semen from the penile urethra during ejaculation by adhering to the glans penis. This virtually eliminates the loss of semen samples during collection/ejaculation. Penis or glans penis is neither referenced, taught nor suggested in Fleury.

5) Sample accumulates at the bottom of the funnel as it liquefies without fraction loss, unlike Simmet. This is compatible with sample liquefaction at room temperature. Fraction or fraction loss is neither referenced, taught nor suggested in Fleury.

6) The present invention device allows recording of sample volume after liquefaction. This measurement is useful to patients interested in monitoring this important

parameter in the evaluation of male infertility [ejaculate volume]. Average ejaculate volume combined with sperm count is useful in determining total sperm delivered at ejaculation. This information is vital to couples working through the variables that may affect male infertility. The device may be useful to the couple engaged in home assessment of male infertility.

7) The present invention avoids the inelegance of condom sampling. The device allows spontaneous mixing of sperm rich fractions with seminal plasma for subsequent spermeogram or spermcheck analyses without using a scissor, additional container and loss of semen sample as in the case of condom collection.

8) Semen sampling for microscopic, clinical and biochemical examinations can be performed directly from the present invention device container.

9) The present invention device can be used in hospitals, clinics, labs and most of all at home for sample collection, liquefaction and volume measurement of the ejaculated semen sample. The present invention device can also be used to collect semen following post-coital interruption instead of using a condom.

10) The present invention may be accommodated with a lid for easy transportation of samples to the clinic by mails for test and insemination purposes as well as for cryo-preservation of live sperm cells.

11) The present invention device will not break or fail and can't leak during a semen collection as in the case of condoms.

IV. CLAIMS 11-13 AND 18 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET, CLAIM 16, 26 AND 27 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET IN VIEW OF BAR-ARMI (US 6,129,214), CLAIM 30 AND 31 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET IN VIEW OF ERICSSON ET AL. (US 5,068,089), CLAIM 47-49 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET IN VIEW OF YAP (US 6,113,532), AND CLAIMS 28 AND 29 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET IN VIEW VELAZQUEZ (US 6,699,226) BECAUSE THE APPLIED PRIOR ART AS A WHOLE FAILS TO SUGGEST THE APPLICANTS' INVENTION.

Claims 11-13 and 18 are patentable under 35 U.S.C. § 103 over Simmet, claim 16, 26 and 27 are patentable under 35 U.S.C. § 103 over Simmet in view of Bar-Armi (us 6,129,214).

claim 30 and 31 are patentable under 35 U.S.C. § 103 over Simmet in view of Ericsson et al. (us 5,068,089), claim 47-49 are patentable under 35 U.S.C. § 103 over Simmet in view of Yap (us 6,113,532), and claims 28 and 29 are patentable under 35 U.S.C. § 103 over Simmet in view Velazquez (US 6,699,226) because the applied prior art as a whole fails to suggest the Applicants' invention.

Applicants respectfully submit that claims 11-13, 16, 18, 26, 27, 28, 29, 30, 31, and 47-49 would not have been obvious over Simmet, Bar-Ami, Ericsson, Yap, or Velazquez because the applied prior art fails to teach or suggest the present invention.

The Examiner's reliance on Simmet, Bar-Ami, Ericsson, Yap, or Velazquez does not supply the deficiencies of the disclosures regarding the dependent claims vis-à-vis Applicants' base claim 1. A dependent claim contains all the limitations of the intermediate claim upon which it depends and is non-obvious under Federal Circuit guidelines if the intermediate claim upon which it depends is allowable. Hence, it is the Applicants' position that the cited art as whole fails to teach or suggest the claimed invention within the meaning of 35 U.S.C. § 103 and request that the rejection of dependent claims 11-13, 16, 18, 26, 27, 28, 29, 30, 31, and 47-49 be withdrawn.

V. MPEP SECTION 713: EXAMINERS INTERVIEW IS REQUESTED

Applicant respectfully requests an Examiners Interview and respectfully asks Examiner to contact the Applicants' attorney at the telephone listed below so that an interview may be initiated at the time the Examiner handles this Paper.

VI. CONCLUSION

For the foregoing reasons, Applicants respectfully submit that claims 1, 2, 6-57, 82, and 90-93 are in condition for allowance, and a notice for allowance is solicited.

Should questions arise during examination, the Examiner is welcome to contact the Applicants' attorney at the telephone listed below.

Please charge any excess fees due and credit any overpayment to Charge Account No. 50-0423.

Respectfully submitted,

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